IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
FORT WORTH DIVISION

WULFERIC, LLC,	§	
	§	
Plaintiff,	§	
	§	
v.	§	**Civil Action No. 4:24-cv-01183-O**
	§	
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	§	
	§	
	§	
Defendants.		

MEMORANDUM OPINION & ORDER

Before the Court are Plaintiff's Motion for a Preliminary Injunction, Brief, and Appendix in Support (ECF Nos. 3–5); Defendants' Response (ECF No. 13); and Plaintiff's Reply (ECF No. 22). Also before the Court are Defendants' Motion for Summary Judgment, Brief, and Appendix in Support (ECF Nos. 14–16); Plaintiff's Response (ECF No. 21); and Defendants' Reply (ECF No. 24). Additionally, before the Court are Plaintiff's Cross-Motion for Summary Judgment and Brief in Support (ECF Nos. 20–21) and Defendants' Response (ECF No. 25). Finally, before the Court are Defendants' Notice of Subsequent Authority (ECF No. 26) and Plaintiff's Responses (ECF Nos. 27–28).

At Plaintiff's consent, the Court consolidates Plaintiff's Motion for a Preliminary Injunction with the parties' summary judgment briefing to issue a final decision. Accordingly, for the reasons stated in this opinion, the Court **GRANTS** Plaintiff's Cross-Motion for Summary Judgment (ECF No. 20) and **DENIES** Defendants' Motion for Summary Judgment (ECF No. 14).

I. BACKGROUND

Plaintiff Wulferic, LLC makes and sells tobacco products under the trade name Vapor Lab ("Vapor Lab").[1] It is therefore subject to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq*., as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111–31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387, *et seq.*).[2] In the FDCA, Congress authorized the imposition of civil money penalties through an administrative process for certain violations of the law. *See* 21 U.S.C. § 333(f). The TCA extended this administrative authority to violations relating to tobacco products. *See id.* § 333(f)(9). Pursuant to that authority, the FDA initiated an administrative proceeding against Vapor Lab. Vapor Lab in turn filed this lawsuit as a collateral attack on that proceeding, arguing that the FDCA's civil money penalty provision—and, by extension, the proceeding itself—violates Vapor Lab's Seventh Amendment right to a jury trial.

A. The Regulatory Regime

In accordance with its power to regulate interstate commerce, Congress passed the FDCA in 1938. *See* 75 Pub. L. No. 717, 52 Stat. 1040 (describing the Act as one "[t]o prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics"). Finding that previous efforts to regulate the marketing of tobacco products "failed adequately to curb tobacco use by adolescents," Congress amended the FDCA in 2009 to provide more "comprehensive restrictions on the sale, promotion, and distribution of such products."[3]

Tobacco manufacturers must apply for and receive approval from the Food and Drug Administration ("FDA") before marketing any "new tobacco product." 21 U.S.C. § 387j. If a new

[1] Br. Supp. FDA's Mot. Summ. J. 1, ECF No. 15.
[2] *Id.*
[3] *Id.* at 2 (quoting Pub. L. No. 111–31, § 2(6), (13), 123 Stat. 1777).

tobacco product has not undergone premarket review and received authorization, it is deemed "adulterated." *Id.* § 387b(6). The FDCA makes it unlawful to cause a tobacco product to become adulterated or misbranded after it or its components moved in interstate commerce and while it is held for sale. *Id.* § 331(k).

The FDA is the agency tasked with enforcing this regime. The FDA's Center for Tobacco Products ("CTP") investigates violations of tobacco-product requirements and commences enforcement proceedings within the Departmental Appeals Board ("DAB").[4] Both the FDA and DAB are divisions of the U.S. Department of Health and Human Services ("HHS").[5] Administrative law judges ("ALJs") within the Civil Remedies Division of the DAB preside over the FDA's enforcement proceedings.[6]

The FDA's Commissioner of Food and Drugs is authorized to assess a "civil penalty" or impose a "no-tobacco-sale order" for violations of the premarket requirements.[7] *Id.* § 333(f)(5), (9). "In determining the amount of a civil penalty," the following factors shall be considered: "the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." *Id.* § 333(f)(5)(B).

The FDCA provides a twofold appeals process if a civil money penalty is assessed against a tobacco company. First, the tobacco company may appeal to a panel of three ALJs within the Appellate Division of DAB.[8] After exhausting this administrative process, the tobacco company

[4] FDA's App. Supp. Mot. Summ. J. (King Dec.), App. 22–23, ECF No. 16.
[5] Vapor Lab's Compl. for Decl. & Inj. 2, ¶ 8, ECF No. 1; HHS ORG. CHARTS OFF. OF SEC'Y AND DIVS., https://www.hhs.gov/about/agencies/orgchart/index.html (last visited July 17, 2025).
[6] FDA's App. Supp. Mot. Summ. J. (King Dec.), App. 23, ECF No. 16.
[7] Br. Supp. FDA's Mot. Summ. J. 3, ECF No. 15.
[8] Vapor Lab's Compl. for Decl. & Inj. 8, ¶ 40, ECF No. 1.

may seek judicial review in the United States Court of Appeals for the District of Columbia Circuit or in any other circuit in which the company conducts business. *Id.* § 333(f)(6).

B. The Underlying Administrative Proceeding Against Vapor Lab

On September 16, 2024, the FDA's CTP filed an administrative complaint for a civil money penalty of $20,678 against Vapor Lab in the Civil Remedies Division of the DAB.[9] CTP's administrative complaint alleges that Vapor Lab sells "adulterated" and "misbranded" tobacco products—e-liquids that have not been authorized for sale by the FDA.[10]

On October 21, 2024, Vapor Lab filed its answer to the administrative complaint.[11] In its answer, Vapor Lab stated that it does not waive its Seventh Amendment right to a jury trial and therefore the Seventh Amendment prohibits the DAB from adjudicating its case.[12] The case was assigned to a DAB ALJ for hearing and decision.[13]

On March 10, 2025, CTP moved for summary decision, the administrative equivalent of summary judgment.[14] On March 26, 2025, the ALJ adjudicating the case stayed the hearing pending a ruling on CTP's motion for summary decision.[15] As of June 9, 2025, the ALJ had not yet ruled on CTP's motion for summary decision, and no hearing date had been set.[16]

C. This Lawsuit

On December 3, 2024, Vapor Lab filed this lawsuit against HHS, the Secretary of HHS, the FDA, and the FDA Commissioner (collectively, "FDA").[17] Vapor Lab's Complaint alleges

[9] *See* FDA's App. Supp. Mot. Summ. J., App. 1–7, ECF No. 16.
[10] *Id.* at App. 5.
[11] *See id.* at App. 8–10.
[12] *Id.* at App. 9.
[13] *See id.* at App. 11.
[14] Joint Status Report 1, ECF No. 30.
[15] *Id.*
[16] *Id.*
[17] *See* Vapor Lab's Compl. for Decl. & Inj., ECF No. 1.

that "[u]nder the Supreme Court's ruling in *SEC v. Jarkesy*, . . . Defendants' administrative proceeding violates Plaintiff's right to a jury trial under the Seventh Amendment."[18]

Vapor Lab seeks a declaration that both "the FDCA's civil money penalty *provisions* for tobacco products" and "the FDA's civil money penalty *proceeding* against [Vapor Lab]" violate the Seventh Amendment.[19] Vapor Lab also seeks an injunction: (1) requiring the DAB to dismiss with prejudice the administrative complaint against Vapor Lab; (2) prohibiting HHS and the FDA from adjudicating civil money penalties in the administrative proceeding against Vapor Lab; and (3) prohibiting HHS and the FDA from adjudicating civil money penalties in administrative proceedings entirely.[20]

The parties filed Motions for Summary Judgment.[21] Vapor Lab initially filed a Motion for a Preliminary Injunction, but "consents to the Court consolidating the preliminary injunction motion with the parties' summary judgment briefing to reach a final decision on [Vapor Lab's] claim in accordance with Federal Rule of Civil Procedure 65(a)(2)."[22]

II. LEGAL STANDARDS

A. Subject Matter Jurisdiction

Federal district courts have jurisdiction over cases "arising under" federal law. U.S. CONST. art. III, § 2, cl. 1. With respect to federal agencies, however, Congress can "divest[] district courts of their ordinary jurisdiction" by substituting "an alternative scheme of review" within an agency—where the agency's final decision is reviewable by an Article III court of appeals. *Axon Enter., Inc. v. FTC*, 598 U.S. 175, 185 (2023). Sometimes Congress does so in explicit terms,

[18] *Id.* at 1, ¶ 1.
[19] *Id.* at 12, ¶ 61(a)–(b) (emphasis added). Vapor Lab mistakenly cites 21 U.S.C. § 331(f)(9) as the civil money penalty provision. The correct provision is 21 U.S.C. § 333(f)(9).
[20] *Id.* at 12–13, ¶ 61(c)–(e).
[21] *See* FDA's Mot. Summ. J., ECF No. 14; Vapor Lab's Cross-Mot. Summ. J., ECF No. 20.
[22] Vapor Lab's Combined Br. 1, ECF. No. 21.

"providing in so many words that district court jurisdiction will yield." *Id.* Other times, it does so implicitly, leaving open the question whether the statutory review scheme is exclusive. *Id.*

In the latter case, when a party to an administrative proceeding seeks collateral review in district court, the district court must ask whether the statute precludes its jurisdiction. *Id.* If "the particular claims brought [are] 'of the type Congress intended to be reviewed within this statutory structure,'" the district court should decline to hear the case. *Id.* at 186 (quoting *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 212 (1994)).

To guide this inquiry—and prevent courts from engaging in guesswork about Congress's intent—the Supreme Court in *Thunder Basin* presented three questions: "First, could precluding district court jurisdiction 'foreclose all meaningful judicial review' of the claim?" *Id.* (quoting *Thunder Basin*, 510 U.S. at 212–13). "Next, is the claim 'wholly collateral to [the] statute's review provisions?'" *Id.* (quoting *Thunder Basin*, 510 U.S. at 212 (alteration in original)). "And last, is the claim 'outside the agency's expertise?'" *Id.* (quoting *Thunder Basin*, 510 U.S. at 212–13). "When the answer to all three questions is yes, '[courts] presume that Congress does not intend to limit [the district court's] jurisdiction.'" *Id.* (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 489 (2010)).

Because at issue is the district court's jurisdiction—its very power to hear the case—there is substantial authority that the district court is free to weigh the evidence and satisfy itself as to the existence of its power to hear the case. *Williamson v. Tucker*, 645 F.2d 404, 412–13 (5th Cir. 1981). In short, no presumptive truthfulness attaches to a plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims. *Id.* at 413.

B. Summary Judgment

A movant is entitled to summary judgment if by the pleadings and evidence it can show "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). "[S]ummary judgment is appropriate where the only issue before the court is a pure question of law." *Sheline v. Dun & Bradstreet Corp.*, 948 F.2d 174, 176 (5th Cir. 1991).

III. ANALYSIS

Although the FDCA provides for an internal review process followed by review in a U.S. Court of Appeals *after* a final order has been issued—which does not involve the district courts—Vapor Lab seeks to establish the jurisdiction of this Court to hear its challenge *before* a final order has been issued. The parties agree the statutory review scheme raises a question of implicit, rather than explicit preclusion; therefore, this Court applies the *Thunder Basin* factors to assess its jurisdiction. As the Court will explain, the FDCA does not preclude this Court's jurisdiction over Vapor Lab's challenge. Therefore, the Court proceeds to the merits.

To that end, the Court asks first whether the administrative action against Vapor Lab implicates the Seventh Amendment—an analysis rooted in the text, history, and tradition of the Seventh Amendment. If the action implicates the Seventh Amendment, the Court next asks whether a narrow exception applies. Namely, if the action concerns "public rights," then the matter may be assigned to an agency for adjudication without offending the Seventh Amendment. The Court concludes in turn that the administrative adjudication implicates the Seventh Amendment, and the public rights exception does not apply. Therefore, Vapor Lab is entitled to declaratory and injunctive relief.

A. Jurisdiction

Axon Enterprises v. FTC presents the classic type of challenge that district courts can review on collateral attack, despite the agency's provision of a direct review process after a final order. *See* 598 U.S. at 180 (charging "that the agencies, as currently structured, are unconstitutional in much of their work"). Vapor Lab therefore seeks to align itself with *Axon* to establish this Court's jurisdiction, while the FDA attacks Vapor Lab for its "inapt analogy between this case and *Axon*."[23]

The Court begins with the question whether Vapor Lab's challenge is indeed analogous to *Axon*, or whether it is more like the cases *Axon* distinguished. *See id.* at 186–89. Indeed, before applying the *Thunder Basin* factors, the Supreme Court in *Axon* undertook a "30,000-foot view of the issue" by situating its challenge in relation to others that have been analyzed under *Thunder Basin*. *Id.* at 189. This Court's jurisdictional analysis therefore proceeds in the same manner as *Axon*'s.

1. The "30,000-foot view of the issue"

One way of distilling the implicit-preclusion analysis is to compare Vapor Lab's Seventh Amendment claim to other constitutional claims that have been analyzed under *Thunder Basin*. Two sets of Supreme Court precedent are relevant. In one set of cases—*Thunder Basin* itself and *Elgin v. Department of Treasury*—the Supreme Court concluded that the constitutional claims were subject to the statutory review schemes and thus the district courts lacked jurisdiction. *Thunder Basin*, 510 U.S. at 216; *Elgin v. Dep't of Treasury*, 567 U.S. 1, 23 (2012). In the other—*Axon* and *Free Enterprise*—the Supreme Court decided the constitutional claims stood outside the statutory review schemes because they were challenges to "the structure or very existence of an

[23] *See* FDA's Reply Supp. Mot. Supp. J. 2, ECF No. 24.

agency." *Axon*, 598 U.S. at 189; *Free Enterprise*, 561 U.S. at 491. The Court addresses the latter cases first.

i. *Axon* and *Free Enterprise*

The constitutional challenges in *Axon* and *Free Enterprise* charge that "some fundamental aspect of the [agency's] structure violates the Constitution." *Axon*, 598 U.S. at 182 (double-for-cause removal protections, in violation of Article II's Vesting Clause; and combination of prosecutorial and adjudicatory functions in a single agency, in violation of separation-of-powers principles); *Free Enterprise*, 561 U.S. at 484 (double-for-cause removal protections, in violation of Article II's Vesting Clause).

The challenges are "structural" in two senses. First, they are structural with respect to the *agency*. *Axon* expressly delineates challenges to a "substantive decision" within the agency or to the "commonplace procedures agencies use to make such a decision" from challenges to the "structure or very existence of an agency." *Axon*, 598 U.S. at 189. Second, they are structural with respect to the *Constitution*, as they implicate the division of power between branches. Together, "[t]hey charge that an agency is wielding authority unconstitutionally in all or a broad swath of its work." *Id.*

As *Axon* and *Free Enterprise* show, structural defects present a "fruit-of-the-poisonous-tree" problem. Because part of the agency is tainted, all work carried out under that (unconstitutional) authority is tainted as well. For example, in *Free Enterprise*, the Board's "'freedom from Presidential oversight' rendered unconstitutional 'all power and authority [the Board] exercised.'" *Id.* (quoting *Free Enterprise*, 561 U.S. at 508). "The Article II challenges in [*Axon*] would likewise prevent ALJs—through whom the Commissions do much of their work—from exercising any power, unless they lose their double-for-cause tenure protection." *Id.*

Finally, "being subjected to unconstitutional agency authority" in an administrative proceeding is a "here-and-now injury." *Id.* at 191 (internal quotation marks and citation omitted). Because "[a] proceeding that has already happened cannot be undone," an agency's direct review scheme should pose no independent bar to district court jurisdiction. *Id.* In other words, a person subject to such proceedings has a "right[] not to undergo the complained-of agency proceedings" and should be able to assert that right on collateral review in district courts. *Id.* at 192.

ii. *Thunder Basin* and *Elgin*

Not all constitutional challenges involving federal agencies are reviewable by district courts. Take *Thunder Basin*, for example, where a coal company brought a pre-enforcement challenge to its statutory obligations under the Mine Act. *Thunder Basin*, 510 U.S. at 204–05. Although the Mine Act funneled challenges through the Federal Mine Safety and Health Review Commission, the coal company sought to challenge the Mine Act first in federal district court. *Id*. The coal company's primary contention was that its obligations under the Mine Act conflicted with its rights under the National Labor Relations Act. *Id*. But it also argued that the Mine Act's "comply-or-incur-penalties" requirement violated the Due Process Clause of the Fifth Amendment because it deprived the coal company of a hearing. *Id.* at 205; *see also Axon*, 598 U.S. at 187.

The Supreme Court held that both claims could be meaningfully reviewed through the statutory review process and thus the district court lacked jurisdiction. *Thunder Basin*, 510 U.S. at 218. The due process challenge was not the only claim raised, nor was it the central claim; rather, "[t]he crux of the dispute" was the alleged conflict between federal labor laws. *Axon*, 598 U.S. at 186. And the "Commission . . . had 'extensive experience' in addressing the statutory issues raised, and could resolve them in ways that 'brought to bear' its 'expertise' over the mining industry." *Id.* at 187. "All that was less so, . . . of the company's constitutional challenge; but that

claim could be 'meaningfully addressed in the Court of Appeals.'" *Id.* The Supreme Court also considered, as a mitigating factor in precluding district court review, that the reviewing court was an "independent commission," rather than "the agency itself." *Thunder Basin*, 510 U.S. at 215.

In *Elgin*, a federal employee was discharged from his employment for failing to register for the draft in accord with federal law. *Elgin*, 567 U.S. at 6–7. He sued in federal district court, arguing that the draft law violated the Equal Protection Clause by excluding women. *Id.* at 7; *see also Axon*, 598 U.S. at 187. The Supreme Court held that the Merit Systems Protection Board ("MSPB") was the exclusive gateway "for reviewing personnel action taken against federal employees" and thus the district court lacked jurisdiction over his claim. *Id.* at 5 (quoting *United States v. Fausto*, 484 U.S. 439, 455 (1988)). The Supreme Court characterized Elgin's constitutional claim as merely the "vehicle" by which he sought to be reinstated and receive backpay—"precisely the type of personnel action regularly adjudicated by the MSPB." *Id.* at 22.

* * *

The Supreme Court in *Axon* framed the challenge in *Elgin* as a challenge to a "substantive decision" of the agency ("firing an employee"). *Axon*, 598 U.S. at 189. Likewise, the Court framed *Thunder Basin*'s due process claim as a challenge to a "substantive decision" of the agency ("fining a company") or to "the commonplace procedures" used by the agency. *Id.* The question, according to *Axon*, is whether the "agency is wielding authority unconstitutionally in all or a broad swath of its work." *Id.* So, if a constitutional challenge implicates the agency's authority, and if the constitutional violation would taint "all or a broad swath of [an agency's] work," then the claim would be like those in *Axon* and *Free Enterprise*. *Id.*

With this context, the Court explains why Vapor Lab's Seventh Amendment challenge is more like *Axon* and *Free Enterprise*, and less like the others.

iii. Vapor Lab's Challenge

The Seventh Amendment provides that "[i]n [s]uits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any court of the United States, than according to the rules of the common law." U.S. CONST. amend. VII. At first glance, Vapor Lab's Seventh Amendment challenge looks a lot like the due process challenge in *Thunder Basin*—both could be framed as alleging that the agency's enabling statute is void of a procedural protection. Indeed, that is how the FDA characterizes Vapor Lab's challenge.[24] But Vapor Lab's claim is not actually about the procedures the FDA uses; it is about the FDA's *power* to adjudicate the action within an administrative tribunal.

Even though Vapor Lab does not bring an Article III challenge per se, a Seventh Amendment challenge to administrative proceedings necessarily raises an Article III challenge. *See SEC v. Jarkesy*, 603 U.S. 109, 120–40 (2024); *see also Gaudet v. United States*, 517 F.2d 1034, 1035 (5th Cir. 1975) ("It is the substance of the claim and not the language used in stating it which controls."). That is because the Seventh Amendment applies to "[s]uits at common law," and "[t]he Constitution prohibits Congress from 'withdraw[ing] from judicial cognizance [i.e., Article III] any matter which, from its nature, is the subject of a suit at the common law.'" U.S. CONST. amend. VII; *Jarkesy*, 603 U.S. at 127 (quoting *Murray's Lessee v. Hoboken Land & Improvement Co.*, 18 How. 272, 284 (1856)). So, if the agency's action qualifies as a suit at common law, then the Seventh Amendment right to a jury trial is triggered *and* adjudication by an Article III court is mandatory.

[24] *See, e.g.*, FDA's Reply Supp. Mot. Supp. J. 2, ECF No. 24 ("On its face, the claim addresses the 'procedures [FDA] use[s] to' determine civil penalty proceedings for TCA violations, a fraction of the agency's work implementing the TCA and a sliver of its overall responsibilities." (quoting *Axon*, 598 U.S. at 189)).

The Supreme Court's recent decision in *SEC v. Jarkesy* illustrates this point. There, the Supreme Court held that when the Securities and Exchange Commission ("SEC") brings an enforcement action seeking civil penalties for fraud, it implicates the Seventh Amendment right to a jury trial. *Jarkesy*, 603 U.S. at 121–26. Because the SEC adjudicated the dispute in its own tribunal,[25] the Court also asked "whether the 'public rights' exception to Article III jurisdiction applies."[26] *Id.* at 120, 127–40. The public rights "exception has been held to permit Congress to assign certain matters to agencies for adjudication even though such proceedings would not afford the right to a jury trial." *Id.* at 120. The Supreme Court decided no such exception to Article III adjudication applied; therefore, the petitioners were "entitled to a jury trial *in an Article III court*." *Id.* at 140 (emphasis added).

Although *Jarkesy* was a Seventh Amendment case, Article III was also a focal point in the Supreme Court's analysis. *All* Justices agreed on why that was. "The Seventh Amendment's jury-trial right does not work alone," Justice Gorsuch explained in his and Justice Thomas's concurrence. *Id.* at 141 (Gorsuch, J., concurring). It works in concert with Article III and the Due Process Clause of the Fifth Amendment to "vindicate the Constitution's promise of a 'fair trial in a fair tribunal.'" *Id.* The majority likewise explained:

> A defendant facing a fraud suit has the right to be tried by a jury of his peers before a neutral adjudicator. Rather than recognize that right, the dissent would permit Congress to concentrate the roles of prosecutor, judge, and jury in the hands of the Executive Branch. That is the very opposite of the separation of powers that the Constitution demands.

Id. at 140 (majority opinion).

[25] *See Jarkesy*, 603 U.S. at 116 ("The SEC may bring an enforcement action in one of two forums. First, the Commission can adjudicate the matter itself. See §§ 77h–1, 78u–2, 78u–3, 80b–3. Alternatively, it can file a suit in federal court. See §§ 77t, 78u, 80b–9.").
[26] The public rights doctrine is discussed *infra* III.B.2.

The dissenting Justices decided the SEC's action concerned public rights, and thus the action could be adjudicated outside of Article III. *Id.* at 197 (Sotomayor, J., dissenting). But despite reaching a different conclusion on that issue, Justice Sotomayor agreed with the remaining Justices on the import of Article III to the analysis. "Although this case involves a Seventh Amendment challenge," Justice Sotomayor explained, "the principal question at issue is one rooted in Article III and the separation of powers." *Id.* at 171. "[A]s the majority rightly acknowledges, the Seventh Amendment's jury-trial right 'applies' only in 'an Article III court.'" *Id*. So, a Seventh Amendment challenge is necessarily a challenge to the *forum* in which the action is being adjudicated. And a conclusion that the forum is appropriate, i.e., "that Congress properly assigned a matter to an agency for adjudication," she explained, "necessarily 'resolves [any] Seventh Amendment challenge.'" *Id.* at 172 (quoting *Oil States Energy Servs., LLC v. Greenes Energy Grp., LLC*, 584 U.S. 325, 345 (2018) (alteration in original)).

Because a Seventh Amendment challenge to an agency proceeding is so closely intertwined with Article III, Vapor Lab necessarily presents a structural constitutional challenge, like those in *Axon* and *Free Enterprise* that attack how the agency is wielding its authority. There are no jury trials in administrative tribunals. So, either Vapor Lab *is* entitled to a jury trial and the FDA's administrative proceeding must cease, or Vapor Lab is *not* entitled to a jury trial and the FDA's action can proceed. Either way, because Vapor Lab's claim implicates the FDA's power to proceed at all, Vapor Lab may assert the *Axon* and *Free Enterprise* "here-and-now injury" of subjection to an "illegitimate proceeding." *Axon*, 598 U.S. at 191. That is so even when the defect is found in the forum rather than the decisionmaker.

Here, too, the difference between Vapor Lab's claim and *Thunder Basin*'s due process challenge becomes clearer. There were no proceedings to challenge in *Thunder Basin*. Indeed, the

whole point of the due process challenge to the statute was that it permitted the agency to impose a fine *without* process. The coal company thus could not claim the *Axon* and *Free Enterprise* here-and-now injury of subjection to an illegitimate proceeding. Nor had the coal company been fined yet. *Thunder Basin*, 510 U.S. at 216. The coal company tried to frame its injury as a Hobson's Choice between complying with the statute and suffering hardship, or not complying and getting fined. *Id*. at 205. But the Supreme Court found the factual record did not support such an injury. *Id.* at 216–18. Therefore, the agency would have to make the substantive decision of imposing a fine first.

By contrast, Vapor Lab does not have to wait until the agency takes some concrete action—engaging in factfinding or imposing a fine—before it can be heard on its constitutional challenge. "What makes the difference here is the nature of the claims and accompanying harms that [Vapor Lab is] asserting." *Axon*, 598 U.S. at 192. Vapor Lab's claim is that the underlying adjudication is occurring in a forum that deprives Vapor Lab of its right to a jury trial.[27] Its corresponding injury is subjection to a potentially illegitimate proceeding, based on a potentially illegitimate forum. Under *Axon* and the precedents *Axon* relied on, this is a legally cognizable injury. *See id.* at 191.

It should be evident, then, why Vapor Lab's challenge is more like the constitutional challenges in *Axon* and *Free Enterprise*, and less like those in *Thunder Basin* and *Elgin*.[28] Nonetheless, one difference is worth mentioning: The constitutional violations occur at different levels of the agencies. In *Axon* and *Free Enterprise*, the "taint" spawned from unconstitutional tenure protections for officials at the highest level of the agencies. *See Free Enterprise*, 561 U.S.

[27] In Vapor Lab's words, its "claim is that Congress violated the Constitution (the Seventh Amendment) by authorizing FDA to levy civil money penalties in an administrative forum"—an allegation "that the administrative proceeding itself is unconstitutional." Vapor Lab's Combined Br. 8, ECF. No. 21.

[28] The equal protection challenge in *Elgin* can be summarily disregarded, because it was not an attack on the agency itself. Rather, it was a challenge to the statutory authorization for an employment decision that was within the scope of the agency's review. *Elgin*, 567 U.S. at 23.

at 508 (the Board); *Axon*, 598 U.S. at 189 (ALJs, "through whom the Commissions do much of their work"). By contrast, here, the taint would appear in a more particular sense; that is, in every proceeding seeking civil money penalties. But the Court sees no reason why this difference is material.

For a claim to implicate *Axon* and *Free Enterprise*, it must only charge that an agency is wielding unconstitutional authority in "all or a broad swath of [an agency's] work." *Axon*, 598 U.S. at 189. By the FDA's own admission, it does. The FDA explains that "[c]ivil money penalties are one of CTP's most impactful enforcement tools."[29] Specifically, "[t]hrough November 30, 2024, CTP has brought 35,883 total civil money penalty actions."[30] Given the sheer volume of civil money penalties the FDA says it brings, a claim that those proceedings are illegitimate indeed strikes at "a broad swath of its work." *Id.*

All of this is to say: Vapor Lab's challenge is like those in *Axon* and *Free Enterprise*, over which the district courts had jurisdiction. And this "30,000-foot view" should "end[] up a good proxy" for the analysis under *Thunder Basin*. *Id.*

2. *Thunder Basin* Factors

Indeed, application of the *Thunder Basin* factors produces the same result as the "30,000-foot view." *Axon*, 598 U.S. at 189. "Each of the three *Thunder Basin* factors signals that a district court has jurisdiction to adjudicate" Vapor Lab's claim. *Id.*

i. Whether Precluding District Court Jurisdiction Could Foreclose All Meaningful Judicial Review

"The first *Thunder Basin* factor recognizes that Congress rarely allows claims about agency action to escape effective judicial review." *Axon*, 598 U.S. at 186. On this point, the FDA argues

[29] Br. Supp. FDA's Mot. Summ. J. 4, ECF No. 15.
[30] *Id.*

that *Jarkesy* is demonstrative.[31] Unlike this case, "the Seventh Amendment claim [in *Jarkesy*] reached the Supreme Court *after* direct review by the Fifth Circuit of the [SEC's] final order."[32] Because the FDA's direct review process is similar to the SEC's, the FDA argues that Vapor Lab could seek judicial review of its Seventh Amendment claim in the same manner that the *Jarkesy* petitioners did.[33] In other words, precluding district court jurisdiction now would not "foreclose all meaningful judicial review." *Thunder Basin*, 510 U.S. at 212–13.

The FDA's argument is too presumptuous. Because the FDCA conditions review on an *adverse* final order, the FDA assumes it will prevail in its action against Vapor Lab. *See* 21 U.S.C. § 333(f)(6) ("Any person . . . who is *aggrieved by* an order assessing a civil penalty . . . may file a petition for judicial review of such order." (emphasis added)). But if Vapor Lab prevails, it will be estopped from ever asserting its Seventh Amendment challenge. Collateral review guarantees Vapor Lab that opportunity.

Even if the FDA does prevail and Vapor Lab appeals the adverse final order, "[j]udicial review . . . would come too late to be meaningful." *Axon*, 598 U.S. at 191. That is because, as *Axon* acknowledges, "[a] proceeding that has already happened cannot be undone." *Id.* Nothing, short of enjoining the proceedings entirely, would redress Vapor Lab's injury of subjection to illegitimate proceedings, if indeed they are illegitimate.[34]

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[31] FDA's Resp. Vapor Lab's Mot. Prelim. Inj. 11–12, ECF No. 13.
[32] *Id.* at 11(emphasis added).
[33] *Id.* at 12.
[34] The FDA's argument that a pure Seventh Amendment injury can be remedied by vacatur of a final order and a new jury trial is beside the point, because that is not the precise injury Vapor Lab claims. *See* FDA's Reply Supp. Mot. Summ. J. 3–4, ECF No. 24. But even assuming it were, it is *far* from clear that "an after-the-fact jury trial could . . . satisfy the demands of the Constitution." *AT&T, Inc. v. FCC*, 135 F.4th 230, 242 (5th Cir. 2025) (citing a lack of "authority supporting the proposition that the constitutional guarantee of a jury trial is honored by a trial occurring after an agency has already found the facts, interpreted the law, adjudged guilt, and levied punishment").

In any event, the first *Thunder Basin* factor is not concerned with whether a plaintiff could obtain meaningful *relief* through the statutory review scheme, but whether the plaintiff could obtain meaningful *review*. *Thunder Basin*, 510 U.S. at 212–13. Because there is some possibility that judicial review of Vapor Lab's claim could be foreclosed if not heard now, the first *Thunder Basin* factor weighs in favor of this Court's jurisdiction.

ii. Whether the Claim is Wholly Collateral

Axon holds that a challenge is necessarily "collateral" if it challenges the agency's power to proceed at all. 598 U.S. at 192–93. So, here, where Vapor Lab's challenge is to the FDA's power to proceed, it is collateral.

The FDA nonetheless asserts that Vapor Lab's claim "is entirely contingent upon" how the underlying proceedings unfold.[35] According to the FDA, Vapor Lab's Seventh Amendment claim is "only" about "the resolution of factual disputes by an administrative decisionmaker."[36] Therefore, the right to a jury trial can only be infringed upon a specific event—factfinding—and not as soon as the proceeding commences, as in *Axon*.[37] Indeed, the FDA argues the right may never "accrue" if the case is decided on the agency's equivalent of summary judgment (i.e., without any factfinding).[38]

The Seventh Amendment may operate like this in an Article III court, but not in an administrative tribunal, where there are no jury trials. If Vapor Lab is entitled to a jury trial, then Vapor Lab is necessarily entitled to an Article III adjudication, and the agency adjudication must cease. So, the collateral factor favors Vapor Lab for the same reason as in *Axon*, where the plaintiffs

[35] FDA's Reply Supp. Mot. Summ. J. 5, ECF No. 24. The FDA does *not* argue that Vapor Lab lacks standing or that this case is not ripe.
[36] *Id.*
[37] *Id.* at 4.
[38] *Id.*

were "challenging the Commissions' power to proceed at all, rather than actions taken in the agency proceedings." *Id.* at 192.

iii. Whether the Claim is Outside the Agency's Expertise

"The second and third [*Thunder Basin* factors] reflect in related ways the point of special review provisions—to give the agency a heightened role in the matters it customarily handles, and can apply distinctive knowledge to." *Axon*, 598 U.S. at 186. Here, because this challenge raises complex "questions of administrative and constitutional law, detached from considerations of agency policy," it falls outside the FDA's expertise. *Id.* at 194 (internal quotation marks omitted).

* * *

For the foregoing reasons, the Court concludes that Vapor Lab's Seventh Amendment challenge is not "the type" that Congress intended to be reviewed within the statutory scheme. *Thunder Basin*, 510 U.S. at 212. Thus, the Court has jurisdiction to review the challenge now.

B. Summary Judgment

Having established this Court's jurisdiction, the Court turns to the merits: whether the FDCA's civil money penalty provision, 21 U.S.C. § 333(f)(9), and the FDA's proceeding against Vapor Lab violate the Seventh Amendment.[39] The analysis is twofold. "The threshold issue is whether this action implicates the Seventh Amendment." *Jarkesy*, 603 U.S. at 120. If the action "does implicate the Seventh Amendment, [the Court] next consider[s] whether the 'public rights' exception to Article III jurisdiction applies." *Id.* If the public rights exception applies, the Seventh Amendment is not offended.

[39] Vapor Lab's Compl. for Decl. & Inj. 12, ¶ 61(a)–(b), ECF No. 1.

1. The Seventh Amendment

The first question is whether the FDA's enforcement proceeding qualifies as a "[s]uit at common law" such that the Seventh Amendment is implicated. U.S. CONST. amend. VII. "[A] jury trial was customary in suits brought in the English law courts," but "cases tried in courts of equity or admiralty [did] not require a jury trial." *Tull v. United States*, 481 U.S. 412, 417 (1987). Thus, the Seventh Amendment applies to suits traditionally decided in English law courts. *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 42 (1989).

On this question, courts have been instructed to decide whether the cause of action and the remedy it provides have common law analogues. *Id.* "First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity. Second, we examine the remedy sought and determine whether it is legal or equitable in nature." *Tull*, 481 U.S. at 417–18. Because some causes of action sound in both law and equity, the remedy is the "more important" consideration. *Jarkesy*, 603 U.S. at 123 (citation omitted).

In *Jarkesy* and a recent Fifth Circuit case involving a Seventh Amendment challenge to the Federal Communications Commission's civil money penalty proceedings, the remedy was "all but dispositive." *See id.* at 123 ("[C]ivil penalt[ies are] a type of remedy at common law that could only be enforced in courts of law." (citation omitted) (second alteration in original)); *AT&T, Inc. v. FCC*, 135 F.4th 230, 236 (5th Cir. 2025) ("The Commission's civil penalties 'are the prototypical common law remedy.'"). There is no reason to suppose that this civil penalty remedy should be any different.

Indeed, the civil money penalty scheme here shares the same features as that in *Jarkesy*. First, the penalty is "designed to punish or deter the wrongdoer" by requiring consideration of such factors as the "gravity of the violation . . . history of prior such violations, [and] the degree of

culpability." *Jarkesy*, 603 U.S. at 123; 21 U.S.C. § 333(f)(5)(B). Second, there are "enhanced" penalties for certain intentional violations. *See Jarkesy*, 603 U.S. at 124; 21 U.S.C. § 333(f)(9)(B). Third, this scheme is not intended to "restore the status quo" by returning money to victims; rather, the collections are "deposited as miscellaneous receipts in the Treasury of the United States." *Jarkesy*, 603 U.S. at 124; 21 C.F.R. § 17.54. Thus, the FDCA's civil money penalty remedy is legal in nature, like those in *Jarkesy* and *AT&T*.

In both of those cases, too, the cause of action had a clear common law analogue. *See Jarkesy*, 603 U.S. at 125–26 (fraud); *AT&T*, 135 F.4th at 237–38 (negligence). But here, Vapor Lab struggles to identify common law roots for the FDA's cause of action. In essence, the FDA's cause of action is a licensing requirement. Tobacco manufacturers must apply for and receive approval from the FDA before marketing any "new tobacco product." 21 U.S.C. § 387j. If a new tobacco product has not undergone premarket review and received authorization, it is deemed "adulterated." *Id.* § 387b(6). The FDA in turn has a cause of action against a company that causes a tobacco product to become adulterated (i.e., fails to obtain a license) while it is held for sale after shipment of one or more of its components in interstate commerce. *Id.* § 331(k).

Vapor Lab does not argue that garden-variety common law causes of action like fraud or negligence are analogous to this scheme. *Cf. Jarkesy*, 603 U.S. at 125–26 (fraud); *AT&T*, 135 F.4th at 237–38 (negligence). Instead, Vapor Lab cites: (1) a 1785 Massachusetts statute authorizing criminal penalties for selling any "diseased, corrupted, contagious, or unwholesome provisions"; (2) a 1787 South Carolina case concerning a person criminally charged with selling liquor without a license; and (3) a 1787 Pennsylvania case of a ship owner who transported goods without paying taxes and thus faced statutory forfeiture of his ship.[40]

[40] Vapor Lab's Br. Supp. Mot. Prelim. Inj. 8, ECF No. 4.

Whether the statutes referenced in these examples "target the same basic conduct" as the FDA's cause of action, they are deficient as an evidentiary matter. *Jarkesy*, 603 U.S. at 125. The Seventh Amendment recognizes the right to a jury trial in civil "[s]uits at common law," but Vapor Lab's examples involve cases of criminal and admiralty jurisdiction. U.S. CONST. amend. VII. Moreover, Vapor Lab offers no evidence of *English* causes of action decided in courts of law. *See Tull*, 481 U.S. at 417 ("First, we compare the statutory action to 18th-century actions brought in the courts of England prior to the merger of the courts of law and equity."); *Capital Traction Co. v. Hof*, 174 U.S. 1, 7–8 (1899) ("[T]he seventh amendment, . . . had in view the rules of the common law of England, and not the rules of that law as modified by local statute or usage in any of the states.").

In any event, because "the relief sought is '[m]ore important' than finding a precisely analogous common-law cause of action," the Court determines that the FDCA's civil money penalty provision implicates the Seventh Amendment. *Tull*, 481 U.S. at 421 (quoting *Curtis v. Loether*, 415 U.S. 189, 196 (1974)). Vapor Lab has the right to a jury trial unless the public rights exception applies.

2. The Public Rights Exception

To say that the Seventh Amendment is "implicated" is not to say the Seventh Amendment is violated. Perhaps it creates a *presumption* that the Seventh Amendment is violated, but that presumption can be defeated if a narrow exception applies. Under the "public rights" exception, "Congress may assign the matter for decision to an agency without a jury, consistent with the Seventh Amendment." *Jarkesy*, 603 U.S. at 127. The FDA argues that its action against Vapor Lab

concerns public rights and therefore may be assigned to an agency without a jury.[41] The Court disagrees.

The public rights doctrine is, at its core, an exception to the Article III judicial power. *See Murray's Lessee*, 18 How. at 284. "Under 'the basic concept of separation of powers . . . ,' 'the judicial Power of the United States' cannot be shared with the other branches." *Jarkesy*, 603 U.S. at 127 (quoting *Stern v. Marshall*, 564 U.S. 462, 483 (2011)). But if the matter concerns public rights, an administrative tribunal may adjudicate it without infringing on Article III's judicial power. *Id.* at 128. These are matters that "historically could have been determined exclusively by [the executive and legislative] branches." *Id.* (alteration in original) (quoting *Stern*, 564 U.S. at 493). Categories include "revenue collection, foreign commerce, immigration, tariffs, tribal relations, public lands, public benefits, and patents." *AT&T*, 135 F.4th at 238.

Supreme Court Justices have offered different explanations for the public rights exception. The majority in *Jarkesy* instructed that the doctrine "has no textual basis in the Constitution and must therefore derive instead from background legal principles." *Jarkesy*, 603 U.S. at 131. The majority described *Murray's Lessee*—the Supreme Court's first recognition of the doctrine—as the ideal case to invoke the exception. *Id.* The Court there "took pains to justify the application of the exception in that particular instance by explaining that it flowed from centuries-old rules concerning revenue collection by a sovereign." *Id.* (citing *Murray's Lessee*, 18 How. at 281–85). That is, "there was an unbroken tradition—long predating the founding—of using these kinds of proceedings to 'enforce payment of balances due from receivers of the revenue.'" *Id.* at 128–29 (citing *Murray's Lessee*, 18 How. at 278, 281).

[41] FDA's Resp. Vapor Lab's Mot. Prelim. Inj. 15–17, ECF No. 13.

Relying on *Atlas Roofing v. Occupational Safety and Health Review Commission*, 430 U.S. 442 (1977), the dissent in *Jarkesy* took the opposite view, in which Congress's creation of a new regulatory scheme justifies non-Article III adjudication. *Id.* at 181–82 (Sotomayor, J., dissenting). But the majority's opinion disfavors *Atlas Roofing*, and perhaps even suggests that the Supreme Court "long ago abandoned [*Atlas Roofing*] and its [new regulatory scheme] offshoot." *Kennedy v. Bremerton Sch. Dist.*, 597 U.S. 507, 534 (2022); *see Jarkesy*, 603 U.S. at 138, n.4. Under the majority's history and tradition approach, a new regulatory scheme is precisely a reason *not* to extend the public rights exception. And the majority's opinion in *Jarkesy*—not the dissent's—is the law that binds this Court. After *Jarkesy*, the mandate is clear: "[T]he doctrine is a narrow and extra-textual '*exception*' to presumptively mandatory Article III jurisdiction." *AT&T*, 135 F.4th at 239 (quoting *Jarkesy*, 603 U.S. at 131).

As far as Vapor Lab's Seventh Amendment challenge is concerned, a conclusion that the public rights exception applies necessarily "resolves its Seventh Amendment challenge." *Oil States*, 584 U.S. at 345. That is because "if Congress may assign the adjudication of a statutory cause of action to a non-Article III tribunal, then the Seventh Amendment poses no independent bar to the adjudication of that action by a nonjury factfinder." *Granfinanciera*, 492 U.S. at 53–54. Effectively, "Congress does not violate Article III *or* the Seventh Amendment by authorizing a nonjury factfinder to adjudicate the dispute." *Jarkesy*, 603 U.S. at 172–73 (Sotomayor, J., dissenting) (emphasis added).

The FDA advances several arguments to invoke the public rights exception, but none hold water. First, as a general matter, the FDA argues that the public rights exception applies because the TCA serves a "public-health purpose."[42] The Fifth Circuit made clear in *AT&T*, however, that

[42] *Id.* at 15–16 (quoting *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 438 (5th Cir. 2020)).

it is the substance of the enforcement action, and not the object of the regulations that matters. 135 F.4th at 239–41. Otherwise, "[m]yriad enterprises" could be said to promote public health, which "would blow a hole in what is meant to be a narrow exception to Article III." *Id.* at 239.

Additionally, the Supreme Court precedents relied on by the FDA weakly, if at all, support a "public health" category of public rights. The FDA cites *Crowell v. Benson* as a case that included "public health" among "matters that may be assigned to the Executive Branch for determination."[43] 285 U.S. 22, 51 (1932) ("Familiar illustrations of administrative agencies created for the determination of such matters are found in connection with the exercise of the congressional power as to interstate and foreign commerce, taxation, immigration, the public lands, *public health*, the facilities of the post office, pensions, and payments to veterans." (emphasis added)). But *Crowell* itself concerned the administration of public lands, so it did not adopt a public health category of public rights. *See Jarkesy*, 603 U.S. at 130.

And the case *Crowell* cited, *Houston v. St. Louis Independent Packaging Co.*, which the FDA also relies on, was not about Article III delegation or the Seventh Amendment.[44] 249 U.S. 479 (1919). Indeed, there was no agency enforcement action against anyone. A sausage manufacturer brought a pre-enforcement challenge, presenting the question whether the Secretary of Agriculture exceeded his authority in making a finding of fact to support his promulgation of a meat-labeling regulation. *Id.* at 480–81, 82–83. *Houston* at most is an example of an executive official exercising delegated legislative authority. *Cf. Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 443 (5th Cir. 2020) ("In the TCA, Congress delegated to the Secretary the power to 'deem' which tobacco products should be subject to the Act's mandates."). But *Houston* is not about the public rights exception to Article III, and, aside from *Crowell*, the Supreme Court has never mentioned it as such a case.

[43] *Id.*
[44] *Id.*

It is telling that the Supreme Court in *Jarkesy* did not revisit any of these so-called "public health" cases when discussing the "historic categories of adjudications fall[ing] within the exception."[45] *Jarkesy*, 603 U.S. at 130. Likewise, in *AT&T*, the first case in this Circuit to apply *Jarkesy*, the Fifth Circuit did not recite "public health" among the recognized categories of public rights. *AT&T*, 135 F.4th at 238.

Indeed, the power to promote public health is a police power retained by the states, through the Tenth Amendment, and has never been a distinctive prerogative of the federal government. *See Lane v. United States*, 612 F. Supp. 3d 659, 665 (N.D. Tex. 2020) ("[T]he Supreme Court in *United States v. Lopez* observed that the Constitution withheld from Congress a plenary police power." (internal quotation marks and citation omitted)). So, here, even though the FDA is a federal agency that serves a "public-health purpose," the agency operates pursuant to Congress's delegation of authority under the Interstate Commerce Clause. *Big Time Vapes*, 963 F.3d at 438. The FDA does not advance any argument based on its delegated authority to regulate interstate commerce, however.[46]

Because this "action does not fall within any of the distinctive areas involving governmental prerogatives where the [Supreme] Court has concluded that a matter may be resolved outside of an Article III court, without a jury," the public rights exception does not apply. *Jarkesy*, 603 U.S. at 120.

[45] The FDA also cites *Thomas v. Union Carbide Agricultural Products*, apparently because it involves public health, but the FDA does not explain why that case governs. *See* 473 U.S. 568 (1985).

[46] Some scholars propose that the public rights exception contemplates a licensing regime. That is, if Congress has the power to regulate interstate commerce, it also can condition trade of certain goods on obtaining a license. *See* Will Baude, *The Seventh Amendment, Private Rights, and Administrative Penalties*, REASON: VOLOKH CONSPIRACY (December 8, 2023, at 11:50 AM), https://reason.com/volokh/2023/12/08/the-seventh-amendment-private-rights-and-administrative-penalties/ (citing John Harrison, *Public Rights, Private Privileges, and Article III*, 54 GA. L. REV. 143, 196–99 (2019)).

IV. REMEDIES

A. Declaratory Judgment

Vapor Lab is entitled to declaratory relief in this case. Under the Declaratory Judgment Act, a federal court "may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). "Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such." *Id.* The Declaratory Judgment Act is "an enabling Act, which confers . . . discretion on the courts rather than an absolute right upon the litigant." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995) (citation omitted).

Vapor Lab successfully establishes that the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 333(f)(9), violate the Seventh Amendment, and, therefore, so do the FDA's proceedings against it. Accordingly, the Court **DECLARES** that the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 333(f)(9), violate the Seventh Amendment to the Constitution. The Court also **DECLARES** that the FDA's civil money penalty proceeding against Vapor Lab violates the Seventh Amendment to the Constitution.

B. Permanent Injunction

Vapor Lab is entitled to permanent injunctive relief. A permanent injunction is proper when a plaintiff prevails on the merits, there is no adequate remedy at law for the plaintiff's otherwise irreparable injury, the balance of the harms favors the plaintiff, and an injunction would serve the public interest. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). When the government is the defendant, the balance of harms and the public interest factors "merge." *Nken v. Holder*, 556 U.S. 418, 435 (2009).

Vapor Lab satisfies each of these elements. The Court need not reiterate why Vapor Lab succeeds on the merits of its claim[47] or why Vapor Lab's injury is a "here-and-now injury."[48] Because Vapor Lab can claim a "here-and-now injury" like that in *Axon*, it satisfies the irreparable injury requirement.[49] *See Axon*, 598 U.S. at 191 ("[A]s to that grievance, the court of appeals can do nothing: A proceeding that has already happened cannot be undone. Judicial review of . . . structural constitutional claims would come too late to be meaningful."). As to the final factor, the FDA asks the Court to consider that its regulatory scheme is designed to promote the public interest.[50] But that interest is outweighed, if not negated, by the deprivation of Vapor Lab's Seventh Amendment rights. *See Simms v. District of Columbia*, 872 F. Supp. 2d 90, 105 (D.D.C. 2012) ("It is always in the public interest to prevent the violation of a party's constitutional rights."). Therefore, each of the permanent injunction factors favors Vapor Lab.

Because Vapor Lab carries its burden as to each of the permanent injunction factors, the Court next addresses the scope of the injunction. When ordering equitable relief, the Court is obligated to state "specifically" and "in reasonable detail . . . the act or acts restrained or required" under the injunction. FED. R. CIV. P. 65(d)(1)(b)–(c). The scope of injunctive relief is "dictated by the extent of the violation established." *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979). An injunction "should be crafted to 'provide complete relief to the plaintiffs.'" *Mock v. Garland*, 75 F.4th 563, 587 (5th Cir. 2023) (quoting *Yamasaki*, 442 U.S. at 702). At the same time, the injunction "should be no more burdensome to the defendant than necessary to provide complete

[47] *See supra* III.B.
[48] *See supra* III.A.1.c.
[49] Even if Vapor Lab's sole injury was deprivation of a jury trial, as opposed to subjection to an illegitimate proceeding, a Seventh Amendment injury likely is irreparable, too. *See AT&T*, 135 F.4th at 242; *supra* n.34.
[50] FDA's Resp. Vapor Lab's Mot. Prelim. Inj. 20, ECF No. 13.

relief to the plaintiffs." *Yamasaki*, 442 U.S. at 702. And it must be tailored to "redress the plaintiff's particular injury." *Gill v. Whitford*, 585 U.S. 48, 73 (2018) (citation omitted).

The Court rejects Vapor Lab's request for a nationwide injunction prohibiting HHS and the FDA from adjudicating civil money penalties in administrative proceedings, because it has not shown that relief is "necessary to provide complete relief to [Vapor Lab]." *Trump v. CASA, Inc.*, 145 S. Ct. 2540, 2562–63 (2025). Vapor Lab is the only plaintiff before the Court. So, to provide Vapor Lab complete relief, the Court need only enjoin the FDA from seeking civil money penalties against Vapor Lab. *See id.* at 2557. Accordingly, the Court **ENJOINS** HHS to dismiss with prejudice the administrative complaint against Vapor Lab. The Court also **ENJOINS** HHS and the FDA from adjudicating civil money penalties against Vapor Lab in an administrative proceeding.

C. Attorney's Fees and Costs

The Court denies Vapor Lab's request for attorney's fees and costs at this time. It may file a motion for attorney's fees later.

V. CONCLUSION

Having decided that the Court has jurisdiction to review Vapor Lab's challenge and that Vapor Lab prevails on the merits of its challenge, the Court:

(1) **DECLARES** that the FDCA's civil money penalty provisions for tobacco products, 21 U.S.C. § 333(f)(9), violate the Seventh Amendment to the Constitution;

(2) **DECLARES** that the FDA's civil money penalty proceeding against Vapor Lab violates the Seventh Amendment to the Constitution;

(3) **ENJOINS** HHS to dismiss with prejudice the administrative complaint against Vapor Lab; and

(4) **ENJOINS** HHS and the FDA from adjudicating civil money penalties against Vapor Lab in an administrative proceeding.

The Court shall issue a final judgment separately.

SO ORDERED on this **1st day** of **August, 2025.**

Reed O'Connor
UNITED STATES DISTRICT JUDGE